

## CLAIMS

- 1           1.     A catheter device for penetrating through the wall of a vessel within a  
2           patient's body to a target location outside of that vessel, said device comprising:  
3                 a catheter body having a proximal end and a distal end, the catheter  
4           body being advanceable into the vessel;  
5                 a tissue penetrator that is passable from the catheter body, through the  
6           wall of the vessel and to the target location outside the vessel;  
7                 catheter orientation apparatus comprising at least one of i) an imageable  
8           marker indicative of the direction in which the tissue penetrator will pass from  
9           the catheter body and ii) an imaging apparatus for imaging at least the target  
10          location prior to passage of the tissue penetrator from the catheter body; and,  
11                 a stabilizer that is radially extendable from the catheter body to deter at  
12          least some movement of the catheter body within the vessel as the penetrator  
13          penetrates through the wall of the blood vessel.
- 1           2.     The catheter of claim 1, wherein the stabilizer is expandable.
- 1           3.     The catheter of claim 2, wherein the stabilizer comprises an apparatus  
2           selected from the group consisting of:  
3                 at least one balloon;  
4                 at least one cage structure that is deployable laterally from  
5                 the catheter body;  
6                 at least one member that is deployable laterally from the  
7                 catheter body; and,  
8                 a portion of the catheter body that is initially in a first non-  
9                 stabilizing configuration and is subsequently transitionable  
10                to a stabilizing configuration.

- 1           4.     The catheter of claim 3, wherein the stabilizer expands concentrically  
2                   about the catheter body.
- 1           5.     The catheter of claim 4, wherein the stabilizer is located within a distanc  
2                   no greater than about three times the diameter of the catheter from a  
3                   location at which the penetrator exits the catheter body.
- 1           6.     The catheter of claim 4, wherein the stabilizer substantially surrounds a  
2                   location at which the penetrator exits the catheter body and wherein a  
3                   penetrator passageway is formed in the stabilizer to permit the tissue  
4                   penetrator to pass herethrough.
- 1           7.     The catheter of claim 3, wherein the stabilizer expands non-  
2                   concentrically about the catheter body such that a location at which the  
3                   penetrator exits the catheter body is located closely adjacent to or in  
4                   contact with the blood vessel wall when the stabilizer is expanded.
- 1           8.     The catheter of claim 7, wherein the stabilizer extends axially on both  
2                   sides of a location at which the penetrator exits the catheter body.
- 1           9.     The catheter of claim 1, wherein the stabilizer device comprises a shape  
2                   memory alloy element that is initially disposed in a first configuration  
3                   whereby the stabilizer is not deployed and is subsequently transitionable  
4                   to a second configuration whereby the stabilizer is deployed.
- 1           10.    The catheter of claim 1, wherein the stabilizer comprises at least two  
2                   stabilizer members provided on the catheter, at least one of said  
3                   stabilizer members being proximal to and at least one of said stabilizer

4 members being distal to a location at which the penetrator exits the  
5 catheter body.

1 11. The catheter of claim 1, wherein the stabilizer is further constructed to  
2 straighten a portion of the catheter body when the stabilizer is deployed.

1 12. The catheter of claim 1, wherein the stabilizer is constructed and  
2 deployed in a manner that allows some body fluid to flow through the  
3 vessel, past the stabilizer, when the stabilizer is deployed.

1 13. The catheter of claim 1 wherein the orientation apparatus comprises at  
2 least one penetrator direction marker is formed on the stabilizer, said at  
3 least one penetrator direction marker being useable in conjunction with  
4 an imaging device, to orient the catheter body within the vessel such that  
5 the penetrator will pass into the target location.

1 14. The catheter of claim 13 wherein the penetrator direction marker is  
2 formed on the stabilizer at a location that is radially opposite the location  
3 at which the penetrator passes from the catheter body.

1 15. The catheter of claim 13 wherein the at least one penetrator direction  
2 marker  
3 is imageable by an imaging apparatus positioned outside of the patient's  
4 body.

1 16. The catheter of claim 13 wherein the at least one penetrator direction  
2 marker is imageable by an imaging apparatus positioned on or in the  
3 catheter.

1           17.    The catheter of claim 16 wherein the orientation apparatus of the  
2                    catheter further comprises a lumen for receiving an imaging apparatus  
3                    therewithin such that the imaging apparatus may image the target  
4                    location and at least on penetrator direction marker.

1           18.    The catheter of claim 16 wherein the orientation apparatus of the  
2                    catheter comprises an imaging apparatus mounted in the catheter, said  
3                    imaging apparatus being useable to image the target location and at  
4                    least on penetrator direction marker.

1           19.    A method of deploying a tissue penetrator from a catheter positioned  
2                    within a vessel within a patient's body such that the tissue penetrator  
3                    penetrates through the wall of the vessel to a target location outside of  
4                    the vessel, said method comprising the steps of:

5                            providing a catheter device that comprises a  
6                            catheter body, a tissue penetrator passable from a location on the  
7                            catheter body, at least one catheter orientation apparatus useable  
8                            to orient the catheter such that the tissue penetrator will penetrate  
9                            from the catheter to a desired target location and a stabilizer for  
10                           stabilizing at least a portion of the catheter body within the vessel;

11                           placing the catheter at a desired location within a vessel;

12                           using the catheter orientation apparatus to orient the  
13                           catheter such that the tissue penetrator will enter the target  
14                           locations when the tissue penetrator is subsequently passed from  
15                           the catheter body;

16                           stabilizing the catheter body within the vessel; and

17                           passing the tissue penetrator from the stabilized catheter  
18                           body through the wall of the vessel and to the target location.

- 1           20.    The method of claim 19, wherein the step of stabilizing comprises  
2                   expanding a stabilizer such that the stabilizer is maintained in direct  
3                   contact with the wall of the vessel.
- 1           21.    The method of claim 19, wherein the step of stabilizing comprises  
2                   expanding a stabilizer such that it occupies more of the cross-dimension  
3                   of the vessel lumen than it did prior to expansion.
- 1           22.    The method of claim 19, wherein at least two stabilizer members are  
2                   provided on the catheter, at least one of said stabilizer members being  
3                   proximal to and at least one of said stabilizer members being distal to a  
4                   location at which the penetrator exits the catheter body, and wherein the  
5                   step of stabilizing comprises deploying each of said at least two  
6                   stabilizers.
- 1           23.    The method of claim 19, wherein the stabilizer is further constructed to  
2                   straighten a portion of the catheter body when the stabilizer is deployed,  
3                   and wherein the vessel in which the catheter is positioned is curved such  
4                   that a when the step of advancing is performed a portion of the catheter  
5                   becomes curved in conformity with the curve in the vessel, and wherein  
6                   the step of stabilizing further comprises deploying the stabilizer so as to  
7                   cause at least a portion of the catheter that has become curved to  
8                   assume a substantially straight configuration.
- 1           24.    The method of claim 19, wherein the stabilizer is constructed and  
2                   deployed in a manner that allows some body fluid to flow through the

3 vessel, past the stabilizer, when the stabilizer is deployed and wherein  
4 the step of stabilizing.

1 25. The method of claim 19, wherein the step of stabilizing comprises  
2 expanding a stabilizer such that the stabilizer is closer to the wall of the  
3 vessel than it was prior to expansion but does not remain in abutting  
4 contact with the but does not contact with vessel, and wherein .

1 26. The method of claim 19, wherein the stabilizer is a balloon.

1 27. The method of claim 19, wherein the stabilizer expands concentrically  
2 about the catheter body.

1 28. The method of claim 19, wherein the stabilizer is located within a  
2 distance that is no greater than about three times the diameter of the  
3 catheter from a location at which the penetrator exits the catheter body.

1 29. The method of claim 19, wherein the stabilizer substantially surrounds  
2 a location at which the penetrator exits the catheter body and wherein  
3 a penetrator passageway is formed in the stabilizer and wherein the step  
4 of passing the tissue penetrator comprises passing the tissue penetrator  
5 through said passageway as it passes from the catheter body.

1 30. The method of claim 19, wherein the stabilizer expands non-  
2 concentrically about the catheter body such that a location at which the  
3 penetrator exits the catheter body becomes positioned closely adjacent  
4 to or in contact with the vessel wall when the stabilizer is deployed.

- 1           31.    The method of claim 19 wherein the stabilizer extends axially on both  
2                   sides of a location at which the penetrator exits the catheter body.
- 1           32.    The method of claim 19, wherein the stabilizer comprises a shape  
2                   memory alloy element that has a first non-deployed configuration and a  
3                   second deployed configuration, and wherein the stabilizer is deployed  
4                   by causing the shape memory alloy element to change from its first  
5                   configuration to its second configuration.
- 1           33.    The method of claim 19, wherein at least a pair of spaced stabilizing  
2                   devices are provided on the catheter body on both sides of the exit port,  
3                   said stabilizing devices defining a span of the catheter body  
4                   therebetween, and the method includes stabilizing the span.
- 1           34.    The method of claim 26, wherein the balloon is inflated with imageable  
2                   contrast medium.
- 1           35.    The method of claim 19, wherein the step of orienting the catheter  
2                   comprises imaging the target location and using the image of the target  
3                   location to aim the penetrator at the target location.
- 1           36.    The method of claim 19, wherein the stabilizer is constructed and  
2                   deployed in a manner that allows some body fluid to flow through the  
3                   vessel, past the stabilizer, when the stabilizer is deployed.
- 1           37.    The method of claim 19 wherein the orientation apparatus comprises at  
2                   least one penetrator direction marker formed on the stabilizer and  
3                   wherein the step of orienting comprises imaging said at least one

4 penetrator direction marker and using that image to orient the catheter  
5 body within the vessel such that the penetrator will pass into the target  
6 location.

1 38. The method of claim 19 wherein the penetrator direction marker is  
2 formed on the stabilizer at a location that is radially opposite the location  
3 at which the penetrator passes from the catheter body, and wherein the  
4 step of orienting comprises imaging the target location and the  
5 penetrator direction marker and then rotating the catheter within the  
6 vessel until the distance between the target location and the penetrator  
7 direction marker is maximized, thereby indicating that the penetrator  
8 outlet location is directly aligned with the target location.

1 39. The method of claim 19 wherein the at least one penetrator direction  
2 marker  
3 is imageable by an imaging apparatus positioned outside of the patient's  
4 body, and wherein the step of orienting comprises using an imaging  
5 device positioned outside of the patient's body to image the target  
6 location and at least one penetrator direction marker, then rotating the  
7 catheter until the penetrator direction marker indicates that the  
8 penetrator is directed at the target location.

1 40. The method of claim 19 wherein the at least one penetrator direction  
2 marker is imageable by an imaging apparatus positioned on or in the  
3 catheter, and wherein the step of orienting comprises using an imaging  
4 device positioned on or within the catheter to image the target location  
5 and at least one penetrator direction marker, then rotating the catheter



6 until the penetrator direction marker indicates that the penetrator is  
7 directed at the target location.

1 41. The catheter of claim 40 wherein the orientation apparatus of the  
2 catheter further comprises a lumen for receiving an imaging apparatus  
3 therewithin and the step of orienting further comprises, passing an  
4 imaging apparatus into the lumen, using that imaging apparatus to  
5 image the target location and at least one penetrator direction marker,  
6 then rotating the catheter until the penetrator direction marker indicates  
7 that the penetrator is directed at the target location.

1 42. The method of claim 40 wherein the orientation apparatus of the catheter  
2 comprises an imaging apparatus mounted on or in the catheter, and  
3 wherein the step of orienting comprises using that imaging apparatus to  
4 image the target location and at least one penetrator direction marker,  
5 then rotating the catheter until the penetrator direction marker indicates  
6 that the penetrator is directed at the target location.

1 43. A revascularization procedure comprising the method of claim 19  
2 wherein the vessel in which the catheter is placed is a blood vessel and  
3 the target location is another blood vessel, and wherein a blood flow  
4 path is created between the blood vessels.

1 44. A coronary revascularization procedure comprising the method of claim  
2 43 wherein the catheter is placed in one coronary blood vessel and the  
3 target location is another coronary blood vessel such that a blood flow  
4 path is created between two coronary blood vessels.

- 1        45.    A coronary revascularization procedure comprising the method of claim  
2                    43 wherein the catheter is placed in a coronary blood vessel and the  
3                    target location is a chamber of the heart such that a blood flow path is  
4                    created between the chamber of the heart and the coronary blood  
5                    vessel.
- 1        46.    A TIPS procedure comprising the method of claim 43 wherein the  
2                    catheter is placed in one of the hepatic vein and the portal vein, and the  
3                    target location is the other of said hepatic vein and portal vein, such that  
4                    a such that a blood flow path is created between the hepatic vein and  
5                    the portal vein.
- 1        47.    A TEPS procedure comprising the method of claim 43 wherein the  
2                    catheter is placed in one of the inferior vena cava and the portal vein,  
3                    and the target location is the other of said inferior vena cava and portal  
4                    vein, such that a blood flow path is created between the inferior vena  
5                    cava and portal vein.
- 1        48.    A procedure for creating an arterio-venous fistula comprising the method  
2                    of claim 19 wherein the catheter is placed in one of an artery and vein,  
3                    and the target location is in the other of the artery and vein, and wherein  
4                    the penetration created by the penetrator is used to form a fistula  
5                    between the artery and vein.
- 1        49.    A procedure for delivering a therapeutic or diagnostic substance to a  
2                    target location comprising the method of claim 19 wherein the penetrator  
3                    is a needle having a lumen through which the therapeutic or diagnostic

4 substance may be infused and wherein the catheter body is placed in a  
5 blood vessel near the target location.

1 50. A procedure for gaining access to a target location within a patients body  
2 comprising the method of claim 19 wherein the penetrator is an elongate  
3 penetrating member having a lumen and wherein the method further  
4 comprises passing a guidewire through the lumen of the elongate  
5 penetrating member.

1 51. The method of claim 19 where the inner diameter of the vessel is at least  
2 50% larger than the diameter of the catheter body prior to stabilizing the  
3 catheter body within the vessel.